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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,547	11/19/2003	Alexander Levitzki	27148	5591
7590 Martin D. Moynihan PRTSI, Inc. P. O. Box 16446 Arlington, VA 22215	04/16/2007		EXAMINER TRUONG, TAMTHOM NGO	
			ART UNIT 1624	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS	04/16/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/715,547	LEVITZKI ET AL.
	Examiner Tamthom N. Truong	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 January 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-3,6-11 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3, 6-11 and 28-31 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

### **NON-FINAL ACTION**

It is acknowledged that applicants have elected Group II (claims 1-3, 6-11 and 28-31 (in part), drawn to the preparation of formula II) in the reply of 1-18-07.

Claims 4, 5, 12-27 and 32-34 are withdrawn as being drawn to the non-elected subject matter.

Claims 1-3, 6-11 and 28-31 remain for consideration.

#### ***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-3, 6-11 and 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons applied:

- a. Claims 1, 28 and dependent thereon, the limitation “prodrug” has indefinite metes and bounds because it unclear where the site of functional group for a “prodrug” is. Furthermore, many of the substituents are esters or amide (e.g., carboxy, sulfonamide, etc.) which are typical functional groups for a “prodrug”, and thus, it is unclear if additional ester or amide groups are intended.
- b. In claim 1, the definition of R<sub>1</sub> includes the moiety “guanly” which is not an art-recognized group. It is believed “guanly” is typographical error.

- c. Claim 2 lacks antecedent basis because it depends on claim 1 but recites R<sub>3</sub>, R<sub>5</sub> and R<sub>7</sub> (each) as “a pair of electrons” which is not recited in claim 1. It is unclear if a double bond is intended. Claim 3 is rejected as being dependent on claim 2.
- d. Claim 28 recites the limitation of “enriching” which is unclear if purity is intended or if a different physical forma is intended (e.g., crystalline v. polymorph).
- e. Claim 30 lacks antecedent basis because it depends on claim 28 but recites R<sub>3</sub>, R<sub>5</sub> and R<sub>7</sub> (each) as “a pair of electrons” which is not recited in claim 28. It is unclear if a double bond is intended.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 2. **Lack of Written Description:** Claims 1-3, 6-11 and 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Compound II does not have description in terms of a generic process of making, bioactivity as well as working examples

showing the preferred reagents or reaction condition. Thus, the specification fails to provide written description for compounds of formula II or preparation thereof.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by the following references:

**Mertens et. al. (US 4,954,498):** In column 4, Mertens et. al. disclose a compound of *7,8-dihydro-1H-imidazo[4,5-g]quinazolin-8-one*, a tautomer of Compound II with the following substituents:

- R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>5</sub> and R<sub>7</sub> each represents hydrogen;
- R<sub>6</sub> is hydroxy at the 8-position.

The disclosed compound has pharmaceutical composition, and thus, a preparation thereof is also inherently taught.

**Rewcastle et. al. (J. Med. Chem., 1996, Vol. 39, pp. 918-928):** On page 920, compound 39, a tautomer of Compound II with the following substituents:

- R<sub>1</sub> is an alkyl group;

Art Unit: 1624

- R<sub>2</sub>, R<sub>3</sub>, R<sub>5</sub> and R<sub>7</sub> each represents hydrogen;
- R<sub>6</sub> is hydroxy at the 8-position.

**Alkhader et. al.** (J. of the Chem. Soc., Perkin Trans. 1, Organic & Bio-Org. Chem. (1972-1999), 1979, Vol. 4, pp. 1056-62, or CA 91:123679): On page 1060, compound #9, namely *1,2-Dimethylimidazo[4,5-g]quinazolin-5-one*, which is a tautomer of Compound II with the following substituents:

- R<sub>1</sub> and R<sub>2</sub> each is an alkyl group;
- R<sub>3</sub>, R<sub>5</sub> and R<sub>7</sub> each represents hydrogen;
- R<sub>6</sub> is hydroxy at the 8-position.

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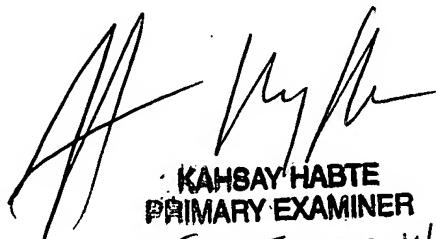
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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4-12-07



KAHSAY HABTE  
PRIMARY EXAMINER  
for James Wilson



Tamthom N. Truong  
Examiner  
Art Unit 1624